

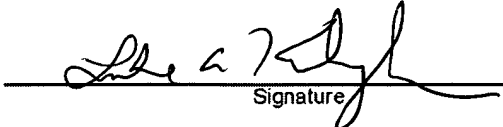
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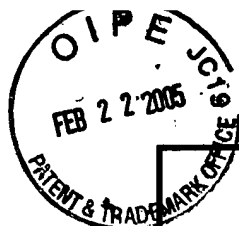
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REQUEST FOR ORAL HEARING BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES		Docket Number (Optional) 3192-002
<p>Date: <u>February 22, 2005</u> Label No. <u>EV567259688US</u> I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 by "Express Mail Post Office to Addressee" service.</p> <p>Donald S. Prater Name (Print) <u>Donald S. Prater</u> Signature</p>		<p>In re Application of Raymond J. Wong</p> <p>Application Number <u>09/996,505</u> Filed <u>November 28, 2001</u></p> <p>For: <u>Cartridges Useful in Cleaning Dialysis Solutions</u></p> <p>Art Unit <u>1723</u> Examiner <u>Krishnan S. Menon</u></p>
<p>Applicant hereby requests an oral hearing before the Board of Patent Appeals and Interferences in the appeal of the above-identified application.</p> <p>The fee for this Request for Oral Hearing is (37 CFR 41.20(b)(3)) <u>\$ 1,000.00</u></p> <p><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: \$ _____</p> <p><input type="checkbox"/> A check in the amount of the fee is enclosed.</p> <p><input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. <u>02/24/2005 HDEMESS1 00000009 09996505</u> <u>01 FC:1403</u> <u>1000.00 DP</u></p> <p><input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.</p> <p><input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0925</u>.</p> <p><input type="checkbox"/> A petition for an extension of time under 37 CFR 1.136(b) (PTO/SB/23) is enclosed. For extensions of time in reexamination proceedings, see 37 CFR 1.550.</p> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>33,251</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> <p><u></u> Signature <u>Luke A. Kilyk</u> Typed or printed name <u>February 22, 2005</u> Date <u>540-428-1701</u> Telephone number</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>		

This collection of information is required by 37 CFR 41.20(b)(3). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FEE TRANSMITTAL for FY 2005

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant Claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$1,000.00)

Complete if Known

Application Number	09/996,505
Filing Date	November 28, 2001
First Named Inventor	Raymond J. Wong
Examiner Name	Krishnan S. Menon
Art Unit	1723
Attorney Docket No.	3192-002

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit AccountDeposit
Account
Number

50-0925

Deposit
Account
Name

Kilyk & Bowersox, P.L.L.C.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee

to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	790	2001	395	Utility filing fee	
1002	350	2002	175	Design filing fee	
1003	550	2003	275	Plant filing fee	
1004	790	2004	395	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$0.00)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below		Fee Paid
Independent	Multiple Dependent	-20**=	-3**=			
				X		
				X		

Multiple Dependent

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	88	2201	44	Independent claims in excess of 3
1203	300	2203	150	Multiple dependent claim, if not paid
1204	88	2204	44	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$0.00)

** or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,370	2453	685	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) Request for Oral Hearing

1000.00

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3)

(\$1,000.00)

SUBMITTED BY

Complete (if applicable)

Name (Print/Type)	Luke A. Kilyk	Registration No. (Attorney/Agent)	33,251	Telephone	540-428-1701
Signature				Date	February 22, 2005

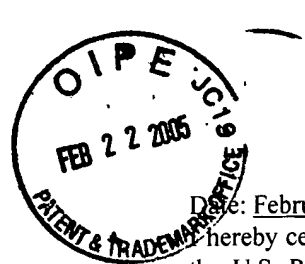
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Date: February 22, 2005 Label No. EV567259688US

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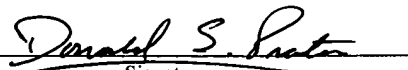
Donald S. Prater
Name (Print)
Signature



Date: February 22, 2005 Label No. EV567259688US

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Donald S. Prater
Name (Print)


Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:	Raymond J. Wong)	Examiner:	Krishnan S. Menon
)		
Application No.:	09/996,505)	Group Art Unit:	1723
)		
Filed:	November 28, 2001)	Confirmation No.:	2941
)		
Docket No.:	3192-002)	Customer No.:	33432

For: CARTRIDGES USEFUL IN CLEANING DIALYSIS SOLUTIONS

APPELLANT'S REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 22, 2005

Sir:

This Reply Brief is in response to the Examiner's Answer dated December 23, 2004. This Reply Brief is being submitted within two (2) months of the date of the Examiner's Answer and therefore is timely. The Board of Patent Appeals and Interferences is respectfully requested to consider the following comments that are in direct response to the Examiner's Answer and are supplemental to Applicant's Supplemental Brief on Appeal filed on November 22, 2004.

The Examiner's comments in response to the Supplemental Brief on Appeal necessitate several comments by the Appellant.

In particular, the Examiner continues to allege that claims 1, 3 - 9, 11, 13 - 16 are obvious under 35 U.S.C. §103(a) over the REDY disclosure (that is, the combined disclosures of

the REDY cartridge) and Polak et al. (U.S. Patent No. 4,650,587), that claim 2 is obvious under 35 U.S.C. §103(a) over the REDY disclosure, Polak et al. and Smakman (U.S. Patent No. 4,542,015), that claims 26 - 28 are obvious under 35 U.S.C. §103(a) over the REDY disclosure, Polak et al. and Potts (U.S. Patent No. 5,234,603), that claims 17 and 18 are obvious under 35 U.S.C. §103(a) over the REDY disclosure, Polak et al. and Marantz et al. (U.S. Patent No. 3,669,880) and that claim 10 is obvious under 35 U.S.C. §103(a) over the REDY disclosure, Polak et al. and Tawil et al (U.S. Patent No. 4,025,608). In addition to repeating the rejections that were made previously, the Examiner has elaborated further on his rationale for combining the references. However, it is respectfully submitted that the Examiner still has not established any convincing teaching or suggestion for combining these references that is sufficient to support a *prima facie* case of obviousness.

The REDY cartridge comprises a specific arrangement of chemical layers, each layer having precisely defined functions.

The REDY cartridge, as shown in Figures 1 and 8 of the present application, and as further shown in the booklets entitled "Guide to Custom Dialysis" and "Sorbent Dialysis Primer" ("the REDY primer"), is a cartridge having a very specific arrangement of chemical layers. Pages 3 - 4 of the REDY primer teach the basic principle of providing a layered cartridge for breaking down and/or adsorbing undesirable components in a used dialysate. The REDY primer teaches that in the operation of the REDY cartridge, used dialysate enters a bottom end of the cartridge and passes through successive layers, which are, in order of flow, a filter pad containing activated carbon, a layer of urease/alumina, a layer of alumina, a layer of zirconium phosphate, a layer of

hydrous zirconium oxide, and a layer of activated carbon (see pages 2 - 5 and Figure 1.2 of the REDY primer). In the operation of the REDY cartridge, since the cartridge is constructed in layers as described in the order of flow, the output of a given layer becomes the input of the next layer in the sequence.

Moreover, the REDY primer teaches the specific function for each layer of the sorbent cartridge in purifying a used dialysate.

The filter pad containing activated carbon serves to remove particulate matter, heavy metals such as copper, mercury and lead (the cartridge is also used to purify water to be used as a dialysate), and oxidizing substances such as sodium hypochlorite.

The urease layer serves to enzymatically convert urea to ammonium carbonate. Ammonium and carbonate ions are carried up to the next layer.

The zirconium phosphate layer serves as a cation exchanger with sodium and hydrogen. Cations such as ammonium are adsorbed by the zirconium phosphate as well as calcium, potassium and magnesium. In exchange, the zirconium phosphate layer releases hydrogen and sodium and acts as a buffer. The relative amounts of sodium and hydrogen depends on factors such as the pH and the presence of anions in the solution.

The hydrous zirconium oxide layer, which contains zirconium oxide in an acetate form, serves as an anion exchanger. It adsorbs negative ions such as fluoride and phosphate and releases acetate. The layer also adsorbs metals such as iron, mercury, lead, and aluminum, which may be present in tap water used to prepare dialysate.

The final carbon layer adsorbs organic metabolites such as creatinine, uric acid and middle-range molecules. It binds these molecules without releasing anything in exchange.

As shown in these pages of the REDY primer and in Figure 1 of the present application, the REDY cartridge does not include any layer that contains sodium zirconium carbonate. None of REDY disclosure provides any teaching or suggestion at all of changing or substituting any of the layers of the REDY cartridge.

The Examiner reads too much into the disclosure of Polak et al.

The Examiner alleges that Polak et al. teaches sodium zirconium carbonate as a phosphate ion absorber and takes the position that this teaching can be combined with the REDY teachings. The Examiner is clearly in error in alleging that these references can be combined. Polak et al. relates primarily to a magnesium phosphate (MGP) product. The sole disclosure of sodium zirconium carbonate in Polak et al. is a single statement that reads "[P]referably, it [MGP] is employed with a phosphate ion adsorber, e.g., the state-of-the-art sodium zirconium carbonate product of the formula $(\text{Na})_A (\text{Zr})_B (\text{CO}_3)_C$, wherein "A" has the value of from about 0.8 to about 1.2, and "C", measured as CO_2 , has the value of from about 0.8 to about 1.2 when "B", measured as ZrO_2 , is assigned the value "1". (Col. 5, line 68 to col. 6, line 9). This single statement is the essential basis of every rejection made by the Examiner in the application.

As an initial consideration, it is respectfully submitted that the teachings of Polak et al. with respect to sodium zirconium carbonate are limited to its presence in a mixture with magnesium phosphate. This can be clearly seen in the sentence of Polak et al. quoted above. Although Polak et al. mentions uses of magnesium phosphate by itself, there is absolutely no teaching in Polak et al. of sodium zirconium carbonate being used by itself in any context. It is only described as being used with magnesium phosphate.

Moreover, the mention in this sentence of the sodium zirconium carbonate as "the state-of-the-art sodium zirconium carbonate product" does not provide any guidance or motivation for separating sodium zirconium carbonate from the magnesium phosphate product and using it separately in any other context. Throughout the entire prosecution of this application, the Examiner, in alleging motivation to use the sodium zirconium carbonate in the REDY cartridge, seems to fixate on this term "state of the art," but the Examiner is clearly reading more meaning into this term than what is actually there. Polak et al. does not provide any basis for its description of sodium zirconium carbonate as state-of-the-art, and in particular, does not specifically state that this description is based on the phosphate adsorption capacity of the material. The term "state of the art" could have other reasonable meanings in this context. For example, the term could mean that the sodium zirconium carbonate of the given formula is particularly compatible with the magnesium phosphate in the composition of Polak et al. or that it has other physical properties that make it particularly suitable for use in the enteric system of the reference. Accordingly, statements made by the Examiner on pages 4, 8, 11, 12, 13, and 19 of the Examiner's Answer that Polak et al. teaches that sodium zirconium carbonate is "state of the art for phosphate adsorption" is clearly an inaccurate reading of Polak et al.

Moreover, the mere mention of sodium zirconium carbonate as a phosphate ion adsorber does not provide guidance or motivation for separating sodium zirconium carbonate from the mixture of magnesium phosphate and combining the separated sodium zirconium carbonate with the REDY cartridge. At pages 12 - 14 of the Examiner's Answer, the Examiner has alleged three ways in which the sodium zirconium carbonate described in Polak et al. could be combined with the REDY disclosure to produce a device within the scope of the broadest claims of the

invention. The Examiner has not established motivation for any of these combinations and, as discussed below, the combinations proposed by the Examiner would result in changes in the principle of operation of the REDY cartridge. Moreover, the Examiner has not shown any teaching in the prior art that would indicate that the combination proposed by the Examiner could be made with a reasonable expectation of success.

Polak et al. does not provide teaching or motivation for substituting sodium zirconium carbonate for all or part of the hydrous zirconium oxide layer of the REDY cartridge.

Hydrous zirconium oxide and sodium zirconium oxide are not “equivalent.”

The Examiner alleges, on pages 9, 11, 13, and 20 of the Examiner's Answer, that because the hydrous zirconium oxide layer has a function to remove phosphate, and because sodium zirconium carbonate has a function to remove phosphate, then hydrous zirconium oxide and sodium zirconium carbonate are “equivalent.” This allegation is clearly unsupported by the teachings of the references and, moreover, the Examiner's reliance on irrelevant case law, particularly *Kemco Sales, Inc. v. Control Papers Co.*, 54 U.S.P.Q.2d 1308 (Fed. Cir. 2000), to support the allegation of equivalence is clearly in error.

In particular, the Examiner's allegation that hydrous zirconium oxide and sodium zirconium carbonate are “equivalent” is erroneously based on a case law definition of equivalence that is applied to determine questions of infringement and is not correctly based on the standards of patentability under 35 U.S.C. §103. Specifically, the Examiner, citing the *Kemco Sales* decision alleges, that sodium zirconium carbonate and hydrous zirconium oxide are equivalent as allegedly performing the identical function in substantially the same way to produce

substantially the same result (see page 9 of the Examiner's Answer). The *Kemco Sales* decision relates to infringement and the definition of equivalents as it applies to 35 U.S.C. §112, sixth paragraph, and the Doctrine of Equivalents, supporting a modified function-way-result test for finding equivalence under 35 U.S.C. §112, sixth paragraph. Contrary to what is alleged by the Examiner on page 21 of the Examiner's Answer, the *Kemco Sales* decision contains no teaching relevant to the issues of patentability in this appeal. On page 21 of the Examiner's Answer, the Examiner makes the clearly erroneous statement that the standard for equivalence is not different for patentability and infringement and states that there is no reason why the MPEP would cite such a case law for guidance on equivalence if the standards were different. The Examiner is clearly in error in this statement. Any relevance that the *Kemco Sales* decision may have to patentability is strictly limited to the determination of equivalents under the specialized provisions of 35 U.S.C. §112, sixth paragraph, relating to means-plus-function claims (see section 2183 of the MPEP). The present application does not contain any means-plus-function claims.

By the Patent Office's own interpretation of the requirements of obviousness, as set forth in MPEP 2144.06, in order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art and cannot be based on the mere fact that the components at issue are functional or mechanical equivalents. In the present application, contrary to what is alleged by the Examiner at page 20 of the Examiner's Answer, there is no art-recognized evidence from Polak et al. and the REDY disclosure that sodium zirconium carbonate and hydrous zirconium oxide are equivalent. Polak et al. does not mention hydrous zirconium oxide and therefore does not support the allegation that hydrous zirconium

oxide and sodium zirconium carbonate are equivalent. As noted above, the REDY disclosure does not mention sodium zirconium carbonate and therefore does not support the allegation that hydrous zirconium oxide and sodium zirconium carbonate are equivalent. On page 20 of the Examiner's Answer, the Examiner cites case law (*Smith, Hackett, and Radler v. Hayashi and Hasegawa*, 209 U.S.P.Q. 754 (Bd. of Pat. App. & Inter. 1980 "*Smith v. Hayashi*") in support of his position that there is art-recognized evidence from Polak et al. and the REDY disclosure that sodium zirconium carbonate and hydrous zirconium oxide are equivalent, but this decision does not support the position taken by the Examiner. In *Smith v. Hayashi*, the "evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography" that was used to establish equivalence between selenium and phthalocyanine as photoconductors was an explicit statement in one of the references that included both selenium and phthalocyanine in a list of photoconductive material that could be used as a photoconductive material. In the present application, on the other hand, there is no statement or suggestion in any of the cited art that sodium zirconium carbonate and hydrous zirconium oxide are equivalent. Therefore, the Examiner's statement on page 20 that there is art-recognized evidence from Polak et al. and REDY that sodium zirconium carbonate and hydrous zirconium oxide are equivalent is not at all supported by the record.

In fact, the prior art cited by the Examiner, together with the disclosure of the present application, clearly show the opposite- that sodium zirconium carbonate and hydrous zirconium oxide are not equivalent. As taught on page 4 of the REDY primer and in the discussion of the REDY cartridge on page 5 of the present application, each of the layers of the REDY cartridge is specifically designed to perform a specific function in a specific sequence in the treatment of the

dialysate. The hydrous zirconium oxide layer, which contains zirconium oxide in an acetate form, serves in the REDY cartridge as an anion exchanger to adsorb negative ions such as fluoride and phosphate and release acetate. The layer also adsorbs metals such as iron, mercury, lead, and aluminum that may be present in tap water used to prepare the dialysate. The released acetate serves as a base to correct for acidosis. Accordingly, the statements made by the Examiner, such as on page 11 and page 21 of the Examiner's Answer that "the" function of the hydrous zirconium oxide layer is to remove phosphate is clearly in error, since it is clearly shown in the REDY disclosure that "the" function of the hydrous zirconium oxide layer in the REDY cartridge is to perform a plurality of chemical operations on the dialysate that enters the layer before the dialysate goes on to the next layer. By contrast, the only property described in Polak et al. for its sodium zirconium carbonate is that it is a phosphate ion adsorber (and, as noted above, this is taught only in the context of a mixture with magnesium phosphate). Polak et al. contains absolutely no teachings as to whether sodium zirconium carbonate would carry out the other functions of the hydrous zirconium oxide layer, such as adsorbing fluoride or metals that may be present in tap water and releasing acetate in exchange. Clearly, it would be impossible for sodium zirconium carbonate to carry out the function of releasing acetate, since it does not contain acetate. Moreover, the specification of the present application, on pages 11 to 13, clearly shows that the sodium zirconium carbonate (or the alkali metal-Group IV B metal carbonate of claim 11), in addition to adsorbing phosphate ions, also performs functions that hydrous zirconium oxide cannot perform, such as acting as a bicarbonate provider or donor. Therefore, the prior art cited by the Examiner, and the disclosure of the present application, clearly show that sodium zirconium carbonate and hydrous zirconium oxide are not equivalent. Accordingly,

there is no basis for the Examiner's position that it would be obvious to use sodium zirconium carbonate instead of hydrous zirconium oxide on the alleged grounds that they are equivalent in function.

The disclosure in Polak et al. that sodium zirconium carbonate adsorbs phosphate ions does not provide motivation to substitute sodium zirconium carbonate for hydrous zirconium oxide.

Further, the Examiner is clearly in error in his allegation, on pages 9, 11, 13, and 19 of the Examiner's Answer, that a person skilled in the art would be motivated to substitute sodium zirconium carbonate for all or part of the hydrous zirconium oxide layer of the REDY cartridge because of the teaching in the REDY disclosure that the hydrous zirconium oxide layer has a function to remove phosphate and the statement in Polak et al. that sodium zirconium carbonate has a function to remove phosphate. It is respectfully submitted that a person skilled in the art, upon reading the REDY disclosure, would understand that the hydrous zirconium oxide layer, which contains zirconium oxide in an acetate form, serves in the REDY cartridge as an anion exchanger to adsorb negative ions such as fluoride and phosphate and release acetate. The layer also adsorbs metals such as iron, mercury, lead, and aluminum that may be present in tap water used to prepare the dialysate. The released acetate serves as a base to correct for acidosis. Such a person skilled in the art, upon reading Polak et al. would only be taught that sodium zirconium carbonate can be combined with magnesium phosphate to adsorb phosphate ions in a magnesium phosphate product that acts as a scavenger of ammonium ions released by the hydrolysis of urea in an enteric system. There is absolutely no teaching in Polak et al. of sodium zirconium carbonate being used by itself in any context. It is only stated as being used with magnesium

phosphate. Accordingly, there is no teaching or suggestion to separate the sodium zirconium carbonate from the magnesium phosphate product of Polak et al. and use the separated sodium zirconium carbonate in the REDY cartridge.

Moreover, a person skilled in the art would not be motivated by the description of "the state-of-the-art sodium zirconium carbonate product" of Polak et al. to add sodium zirconium carbonate to the REDY cartridge. The implication by the Examiner by his emphasis on the term "state of the art" used in Polak et al. seems to be that a person skilled in the art would be especially motivated to use sodium zirconium carbonate in any situation where the adsorption of phosphate ions is required. However, the Examiner is clearly in error in this position since, as discussed above, Polak et al. does not specifically state that the description of its sodium zirconium carbonate as "state of the art" is based on the phosphate adsorption capacity of the material. Therefore, the description of sodium zirconium carbonate in Polak et al. does not supply the motivation that is alleged by the Examiner.

Moreover, a person skilled in the art, being aware of the complex effects of the hydrous zirconium oxide layer on dialysate composition, ion balance, and pH as taught in the REDY disclosure, would not find any teaching whatsoever in Polak et al. that sodium zirconium carbonate would carry out these other functions of hydrous zirconium oxide. Accordingly, a person skilled in the art could not have made a substitution of sodium zirconium carbonate for all or part of the layer of hydrous zirconium oxide with a reasonable expectation of success (keeping in mind that "success" in the context of the hydrous zirconium oxide layer of the REDY cartridge means not just the removal of phosphate, but also the contribution towards the production of the physiologically acceptable dialysate composition, ion balance, and pH as taught in the REDY

disclosure). Further, the substitution of sodium zirconium carbonate for all or part of the hydrous zirconium oxide layer in the REDY cartridge would effect changes in the principle of operation of the REDY cartridge. As discussed above, the REDY disclosure teaches that each of the layers of the REDY cartridge is specifically designed to perform a specific function in a specific sequence in the treatment of the dialysate. Since the sodium zirconium carbonate does not perform all of the described functions of the hydrous zirconium oxide layer, such as the releasing of acetate, and could perform other functions, such as releasing sodium and carbonate, that are not intended in the REDY cartridge, the substitution of sodium zirconium carbonate for all or part of the hydrous zirconium oxide layer the principle of operation of the REDY cartridge would thereby be changed.

Accordingly, there is no basis for the Examiner's allegation that the description in Polak et al. of sodium zirconium carbonate as a phosphate ion adsorber provides motivation to combine the teachings of Polak et al. with the teachings of the REDY cartridge.

Polak et al. does not provide teaching or motivation for combining sodium zirconium carbonate with the hydrous zirconium oxide layer of the REDY cartridge

At page 18 of the Examiner's Answer, the Examiner further alleges that it would be obvious to combine sodium zirconium carbonate with hydrous zirconium oxide in a single layer. In particular, the Examiner alleges that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose, citing *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072 (C.C.P.A. 1980), *In re Crockett and Hulme*, 279 F.2d 274, 126 U.S.P.Q. 186 (CCPA 1960) and *Ex parte Quadranti*, 25 U.S.P.Q.2d 1071 (Bd. Pat. App. & Inter.

1992). The facts of these cases are easily distinguished from the facts of the present invention. In *In re Kerkhoven*, the disputed claims related to a method of preparing a spray dried detergent composition by combining conventional spray-dried detergents. In *In re Crockett*, the disputed claims related to a method of promoting the formation of a nodular structure in cast iron by adding magnesium oxide and calcium carbide, and wherein the prior art taught that each of these individually promote the formation of the nodular structure. In *Ex parte Quadranti*, the disputed claims related to a herbicide composition formed by combining known herbicides. In each of the cases, the disputed claims were found to be obvious. In the present application, on the other hand, as discussed, there is no teaching or suggestion in the prior art of a sorbent cartridge that contains sodium zirconium carbonate. Accordingly, the present invention clearly does not fit the fact pattern of the cited cases, since there is not a teaching in the prior art of a sorbent cartridge containing sodium zirconium carbonate layer that can be combined with a teaching in the prior art of a second sorbent cartridge containing hydrous zirconium oxide to provide a sorbent cartridge containing a mixture of sodium zirconium carbonate and hydrous zirconium oxide. Accordingly, the cases cited by the Examiner do not support the position taken by the Examiner. Moreover, hydrous zirconium oxide and sodium zirconium carbonate are not taught by the prior art to be useful for "the very same purpose," since, as discussed above and as is clearly shown in the REDY disclosure, the hydrous zirconium oxide layer has a purpose of carrying out multiple tasks, whereas sodium zirconium carbonate is taught by Polak et al. as having only one function, the adsorption of phosphate in the presence of magnesium phosphate. Accordingly, a person skilled in the art would not consider that hydrous zirconium oxide and sodium zirconium carbonate are taught to be useful "for the very same purpose."

Accordingly, the teachings of the REDY cartridge and Polak et al. do not establish a *prima facie* case of obviousness for replacing all or part of the layer of hydrous zirconium oxide in the REDY cartridge with sodium zirconium carbonate.

Polak et al. does not provide guidance or motivation for substituting magnesium phosphate and sodium zirconium carbonate for all or part of the zirconium phosphate layer of the REDY cartridge.

The Examiner has also taken the position that one of ordinary skill in the art could substitute magnesium phosphate and sodium zirconium carbonate for the zirconium phosphate layer of the REDY cartridge. (See page 3 of the final Office Action of August 20, 2004.) The Examiner is clearly in error in alleging that Polak et al. teaches or suggests that the magnesium phosphate and sodium zirconium carbonate can be substituted for zirconium phosphate in the REDY cartridge. In particular, as taught on page 4 of the REDY primer and on page 5 of the present application, the zirconium phosphate layer of the REDY cartridge serves to remove ammonia and ammonium ions in exchange for hydrogen and Na^+ . The zirconium phosphate layer also serves to remove calcium, potassium, and magnesium, thereby helping to maintain an electrolyte balance. Carbonate from urea hydrolysis combines with hydrogen in the zirconium phosphate layer to form bicarbonate, which serves as a base to correct for acidosis (see the discussion of page 5 of the present application). Accordingly, it can be seen that the zirconium phosphate layer of the REDY cartridge performs more than one function in the operation of the cartridge, since, in addition to removing ammonia, it also serves as an ion exchange material. Polak et al., on the other hand, teaches that its magnesium phosphate material reacts chemically

with ammonia and does not serve as an ion exchange material (see, for example, col. 4, lines 38 - 48 of Polak et al). Polak et al. specifically states that the magnesium phosphate material does not release sodium and does not adsorb calcium, potassium and magnesium. While these characteristics of the magnesium phosphate material may be an advantage in certain contexts, such as an enteric system as described in Polak et al., the magnesium phosphate material clearly does not fulfill the described functions of the zirconium phosphate layer in the REDY cartridge, even if the magnesium phosphate is combined with sodium zirconium carbonate, which is described in Polak et al. only as being a phosphate ion adsorber. Accordingly, there would be no motivation to substitute the magnesium phosphate material of Polak et al. for the zirconium phosphate of the REDY cartridge, since what are taught as desirable characteristics of zirconium phosphate in the REDY cartridge are taught as undesirable characteristics that are eliminated in the magnesium phosphate material of Polak et al. Further, since Polak et al. states that its material does not perform the function of an ion exchange material that is described as a feature of the zirconium phosphate layer in the REDY cartridge, then Polak et al. clearly teaches away from the substitution of its material for the zirconium phosphate layer. Further, the substitution of magnesium phosphate and sodium zirconium carbonate for the zirconium phosphate layer in the REDY cartridge would change the principle of operation of the REDY cartridge, since Polak et al. explicitly states that its material does not perform the function of serving as an ion exchange material, whereas the zirconium phosphate of the REDY cartridge does perform this function as an essential aspect of the operation of the REDY cartridge. Moreover, in view of the complex effects of the zirconium phosphate on dialysate composition, ion balance, and pH, there is no teaching in the combined references that would indicate that magnesium phosphate and sodium

zirconium carbonate could be substituted for the layer of zirconium phosphate with a reasonable expectation of success.

Accordingly, the teachings of the REDY cartridge and Polak et al. do not establish a *prima facie* case of obviousness for replacing all or part of the layer of zirconium phosphate in the REDY cartridge with a layer of magnesium phosphate and sodium zirconium carbonate.

Polak et al. does not provide guidance or motivation for adding sodium zirconium carbonate as an additional layer to the REDY cartridge.

The Examiner also proposes, on page 13, lines 16 - 18 of the Examiner's Answer, that one could simply add a layer of sodium zirconium carbonate somewhere to the REDY cartridge. The Examiner alleges on page 13, lines 3 - 5, that the disclosed characteristic of sodium zirconium carbonate as a phosphate adsorber provides motivation. The Examiner does not provide any explanation as to why this disclosure would motivate a person skilled in the art to add a layer of sodium zirconium carbonate to the REDY cartridge, and the Examiner is completely in error in making this allegation. In particular, as discussed above, there is no motivation for replacing all or any part of the hydrous zirconium oxide layer with sodium zirconium carbonate, since there is no teaching that sodium zirconium carbonate would perform all of the explicitly defined functions of the hydrous zirconium oxide layer. Moreover, the REDY primer at page 15 discloses that the REDY cartridge maintains the phosphate level in the dialysate near zero. Accordingly, there does not appear to be any need whatsoever for additional removal of phosphate ions beyond what is already provided by the existing layers of the REDY cartridge. As noted above, the Examiner's allegation that Polak et al. teaches that sodium

zirconium carbonate is a "state of the art PO₄ adsorber" is not supported by what is actually stated in Polak et al. In particular, as discussed above, the use of the term "state of the art" in this disclosure of Polak et al. is ambiguous as to exactly what the term applies to and does not necessarily teach that sodium zirconium carbonate is a better adsorber of phosphate than any other material. Further, the Examiner is clearly in error in alleging, on page 13, lines 5 - 7 of the Examiner's Answer, that Polak et al. teaches the use of sodium zirconium carbonate for the removal of urea. The passage of Polak et al. referred to by the Examiner (col. 6, lines 9 - 11) clearly refers to the use of magnesium phosphate (MSP), not sodium zirconium carbonate, to remove urea.

Moreover, there is nothing in the REDY disclosure or in Polak et al. that would teach where and how the material of Polak et al. could be incorporated into the REDY cartridge. As discussed in Appellant's Supplemental Brief on Appeal, Polak et al. shows a combination of magnesium phosphate and sodium zirconium carbonate in the form of a pouch or capsule, wherein the material reacts directly through a membrane wall with a dialysate solution or gastrointestinal tract fluid that is external to the pouch or capsule. As discussed above, the REDY cartridge, on the other hand, is made of carefully selected and defined layers. The significance of the provision of layers in the REDY cartridge is that the layers define a series of operations that act in sequence on a dialysate fluid. As the dialysate passes through the cartridge, each layer receives the dialysate from the previous layer and after reacting with it or altering its composition, allows it to pass on to the next layer. Accordingly, if one were to select a different material for addition to the REDY cartridge, one would have to consider not only the overall result that is desired for the dialysate fluid, but also how the material would work in the precise

context according to where the material is added to the cartridge and the effects that it would have on adjoining layers. Clearly, a new and different material, such as sodium zirconium carbonate or a combination of magnesium phosphate and sodium zirconium carbonate, incorporated into any layer of the REDY cartridge or added as an additional layer between existing layers, would affect the dialysate composition, ion balance, and pH in that layer and in adjoining layers and would have a cascading effect throughout the device. Because Polak et al. does not disclose a layered device, there is no teaching in Polak et al. as to what the effect would be of adding sodium zirconium carbonate into the REDY cartridge at any arbitrary location within the layers of the REDY cartridge and whether the effects would be desirable or undesirable. There is nothing in Polak et al. or the REDY disclosure, in the absence of the applicant's own disclosure in the present application, that provides guidance on how to incorporate a new and different material into the REDY cartridge and still achieve the specific objectives of the REDY cartridge. Therefore, the Examiner's allegation of motivation for adding a layer of sodium zirconium carbonate to the REDY cartridge as an additional layer or as an addition to an existing layer is not supported by anything that is actually contained, taught or suggested in the REDY disclosure or in Polak et al. Moreover, there is nothing in the teachings of the REDY disclosure or in Polak et al. that would indicate that sodium zirconium carbonate could be added to the REDY cartridge with a reasonable expectation of success, since there is no teaching in these references as to whether the overall effect of sodium zirconium carbonate on the operation of the REDY cartridge would be desirable or undesirable. The Examiner's reliance on *In re Keller*, 642 F.2d 413, 208 U.S.P.Q. 871 (CCPA1981), as allegedly teaching that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated

into the structure of the primary reference or that the claimed invention needs to be expressly suggested in any one or all of the reference, but rather that the test is what the combined teachings of the reference would have suggested, is misplaced under the facts of the present application. In *Keller*, the invention was directed to the substitution of a digital counter for an analog counter in a cardiac pacer. In all other aspects, the cardiac pacer of the claimed invention of *Keller* worked the same as the cardiac pacers of the applied references, and therefore, the substitution of a digital counter for an analog counter was found to be obvious, even though the digital counters at the time were more cumbersome than analog counters. This fact situation is clearly different from that of the present invention, since in the present invention, the effect that the addition of sodium zirconium carbonate would have on the REDY cartridge depends on how and where the material is added. Since, as discussed above, Polak et al. provides no guidance as to what the effect would be of adding sodium zirconium carbonate into the REDY cartridge at an arbitrary location within the layers of the REDY cartridge and whether the effects would be desirable or undesirable, the combined teachings of the REDY cartridge and Polak et al. would not have suggested such an addition.

Accordingly, the teachings of the REDY cartridge and Polak et al. do not establish a *prima facie* case of obviousness for adding sodium zirconium carbonate to the REDY cartridge as an additional layer.

Since the Examiner has not established a *prima facie* case of obviousness based on a combination of the REDY disclosure and Polak et al., all of the outstanding rejections based on the combination of the REDY disclosure and Polak et al. must fall. Accordingly, the rejection of claims 1, 3-9, 11, 13-16, 19-25, 29-38, and 50-61 should be reversed.

Additional argument regarding claim 19

Moreover, regarding claim 19, the composition of sodium zirconium carbonate of the claimed invention is clearly different from that defined by the empirical formula of Polak et al. The empirical formula of Polak et al., which is the formula $(\text{Na})_A (\text{Zr})_B (\text{CO}_3)_C$, wherein "A" has the value of from about 0.8 to about 1.2, and "C", measured as CO_2 , has the value of from about 0.8 to about 1.2 when "B", measured as ZrO_2 , is assigned the value "1". The composition of sodium zirconium carbonate defined in claim 19, on the other hand, has from about 2 wt% to about 5 wt% Na^+ ; from about 44 wt% to about 50 wt% ZrO_2 ; from about 12 wt% to about 18 wt% CO_3^{2-} ; and from about 30 wt% to about 40 wt% LOD, based on the weight of the sodium zirconium carbonate. The empirical formula can be calculated from the weight percentages as the following: $\text{Na}_{0.23-0.57} : (\text{ZrO}_2)_1 : (\text{CO}_3)_{0.53-0.79} : \text{H}_2\text{O}_{4.39-5.85}$, which is clearly outside the bounds of the empirical formula of Polak et al. In addition to the difference in the empirical formula, Polak et al. does not teach or suggest a sodium zirconium carbonate that is hydrated (30% to 40% LOD). Accordingly, the combination of the REDY disclosure and Polak et al. does not teach the features of claim 19 and for this additional reason, the rejection of claim 19 should be reversed.

Moreover, as discussed in detail in the Appellant's Supplemental Brief on Appeal and as further discussed below, the additional references cited by the Examiner with respect to certain dependent claims do not overcome the deficiencies of the REDY disclosure and Polak et al. This discussion supplements the discussion of the separate patentability of the various claims as discussed in the Appellant's Supplemental Brief on Appeal.

Additional argument regarding claim 21

Claim 21 is dependent on claim 1 and recites that the sodium zirconium carbonate satisfies at least one of the following characteristics: a phosphate adsorption having a minimum capacity of from about 30 to about 35 mg/PO₄-P/gm SZC; a minimum HCO₃⁻ content of from about 2 to about 4 mEq HCO₃⁻/gm SZC; a leachable Na⁺ content of from about 1.5 to about 2.0 mEq Na⁺/gm SZC; or a pH range of titrated sodium zirconium carbonate of from about 6 to about 7.

The claim therefore represents a selection of particular characteristics of adsorption capacity, carbonate content, sodium content and pH range, which otherwise can vary. Accordingly, the Examiner is clearly in error in alleging that the material properties are inherent.

Additional argument regarding claim 2

In particular, regarding the rejection of claim 2 over the REDY disclosure, Polak et al. and Smakman et al. (U.S. Patent No. 4,542,015), the reasons why the combination of the REDY disclosure and Polak et al. do not teach or suggest a cartridge as in claim 1 wherein one of the layers consists essentially of sodium zirconium carbonate is thoroughly discussed above. The Examiner's answer indicates that Smakman et al. is cited because of a comment about hydrated zirconium oxide to the effect that "a satisfactorily reproducible preparation of hydrated zirconium oxide is found to give quite some problems." (col. 2, line 34 - 36 of Smakman et al.). The Examiner alleges that this statement shows that a satisfactory reproducible preparation of hydrous zirconium oxide is difficult. Applicants do not see why the difficulty that one may have had in producing the material at one time in the past would be considered relevant twenty years

later. Accordingly, Smakman et al., which does not mention sodium zirconium carbonate, does not provide any additional motivation to substitute sodium zirconium carbonate in the REDY cartridge. Therefore, the rejection of claim 2 over the REDY disclosure, Polak et al. and Smakman et al should be reversed.

Additional argument regarding claims 26 - 28

Claims 26 - 28 relate to a sorbent cartridge that further comprises zirconium basic carbonate. Regarding the rejection of claims 26 - 28 over the REDY disclosure, Polak et al. and Potts et al. (U.S. Patent No. 5,234,603), the Examiner alleges that Potts et al. discloses the use of a zirconium carbonate to precipitate heavy metals, transition metals, and organic matter from wastewater streams. (Claims 26 - 28 relate to a cartridge of claim 1 that further comprises basic zirconium carbonate.) The Examiner takes the position that it would be obvious to combine the teachings of Potts et al. with the teachings of the REDY disclosure and Polak et al. for the removal of heavy metal and transition metal ions from a dialysate. As discussed in the Supplemental Brief on Appeal, this rejection is clearly in error. In particular, to serve the function alleged by the Examiner of precipitating heavy metals from waste water and hydrolyzing to form a polymeric oxide chain, the zirconium basic oxide would have to be in the form of material that is dissolved or dispersed in a liquid medium such as a wastewater stream. There is no disclosure or suggestion in Potts et al. of a zirconium basic carbonate as a layer in a sorbent cartridge and there is nothing whatsoever that teaches that it would have any effect on the removal of heavy metals if it is not in an environment such as a liquid medium where it can polymerize to bind and precipitate heavy metals. Accordingly, there is no teaching or suggestion that the effects upon

which the Examiner bases his allegations of motivation would be physically possible in the context of a sorbent cartridge. Moreover, Potts et al. is not combinable with the REDY disclosure for the same reasons discussed with regard to Polak et al. In particular, there is no teaching of the effect that an additional material such as basic zirconium carbonate would have on the dialysate composition, ion balance, and pH as the dialysate passes through the REDY cartridge. Further, the disclosure of Potts et al. is even further removed from the present invention since the zirconium carbonate described in Potts et al. is a soluble salt that functions as a precipitating agent in a liquid medium. Nothing in this disclosure, alone or in combination with anything in the REDY disclosure or Polak et al., teaches or suggests the use of basic sodium carbonate in a sorbent cartridge. Moreover, Potts et al. contains no additional teachings that would support the Examiner's proposed combination of the REDY disclosure and Polak et al. that forms the basis of the rejection of independent claim 1. As discussed above, the Examiner has not established a *prima facie* case of obviousness of independent claim 1 based on a combination of the REDY disclosure and Polak et al. Therefore, the rejection of claims 26 - 28 over the REDY disclosure, Polak et al. and Potts et al. should be reversed.

Additional argument regarding claims 17 and 18

Regarding the rejection of claims 17 and 18 over the REDY disclosure, Polak et al. and Marantz et al. (U.S. Patent No. 3,669,880), the only thing that Marantz et al. adds is a description of a flow distributor and filter pads in a recirculating dialysate system. (Claims 17 and 18 ultimately depend from claim 1 and relate to filter pads and a flow diffuser in a specific cartridge configuration.) Moreover, Marantz et al. contains no additional teachings that would support the

Examiner's proposed combination of the REDY disclosure and Polak et al. that forms the basis of the rejection of independent claim 1. As discussed above, the Examiner has not established a *prima facie* case of obviousness of independent claim 1 based on a combination of the REDY disclosure and Polak et al. Therefore, the rejection of claims 17 and 18 over the REDY disclosure, Polak et al. and Marantz et al. should be reversed.

Additional argument regarding claim 10

Regarding the rejection of claim 10 over the REDY disclosure, Polak et al. and Tawil et al. (U.S. Patent No. 4,025,608), the only thing that Tawil et al. adds is a description of a specific form of zirconium phosphate. (Claim 10 ultimately depends from claim 1 and relates to cartridge that includes zirconium phosphate having an average grain size of about 30 to about 40 microns.) Tawil et al. does not overcome the deficiencies of the REDY disclosure and Polak et al. and contains no additional teachings that would support the Examiner's proposed combination of the REDY disclosure and Polak et al. that forms the basis of the rejection of independent claim 1. As discussed above, the Examiner has not established a *prima facie* case of obviousness of independent claim 1 based on a combination of the REDY disclosure and Polak et al. Therefore, the rejection of claim 10 over the REDY disclosure, Polak et al. and Tawil et al. should be reversed.

CONCLUSION

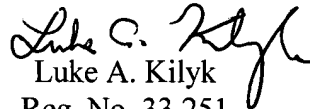
Accordingly, for the reasons set forth in the Brief on Appeal filed on November 22, 2004 and additionally for the reasons set forth herein, it is respectfully submitted that the Examiner's

U.S. Patent Application No. 09/996,505
Appellant's Reply Brief dated February 22, 2005
Reply to Examiner's Answer dated December 23, 2004

rejections of the pending claims are in error and should be reversed.

If there are any additional fees due in connection with the filing of this Reply to Examiner's Answer, please charge the fee to Deposit Account No. 50-0925.

Respectfully submitted,


Luke A. Kilyk
Reg. No. 33,251

Atty. Docket No. 3192-002
KILYK & BOWERSOX, P.L.L.C.
53A East Lee Street
Warrenton, VA 20186
Tel.: (540) 428-1701
Fax: (540) 428-1721